Subcommittee on Investigations and Oversight
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Hearing on:
"Toxic Trailers: Have the Centers for Disease Control Failed to Protect the Public?"

Statement of:

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INTRODUCTION

Good Morning, Chairman Miller, and Ranking Minority Member Mr. Sensenbrenner other distinguished Members of the Subcommittee. I am Christopher De Rosa and I have worked for the Federal Government for 28 years. Today I will respond to the issues posed in your letter of invitation dated February 27, 2008. I would like to note for the record that I am not here as a representative of The Agency for Toxic Substances and Disease Registry (ATSDR) but as an individual scientist. I would also like to emphasize that my remarks today and other stated concerns should in no way be construed as a reflection on the highly talented, motivated and well intentioned staff at all levels of the ATSDR, as well as the Centers for Disease Control and Prevention (CDC).

At present I serve as the Assistant Director for Toxicology and Risk Analysis at the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention. Previously, I served as the Director, Division of Toxicology and Environmental Medicine, Agency for Toxic Substances and Disease Registry (ATSDR) from 1991 to 2007. Prior to my selection as Division Director, I was the Deputy Associate Administrator for Science, also at ATSDR.

After receiving my Masters Degree in Ecology and Ph.D. in Biology from Miami University, Oxford, Ohio, I held academic appointments at the Universities of Virginia and Maine over a period of ten years. Before coming to ATSDR in 1991, I worked for the Environmental Protection Agency's Office of Research and Development (EPA/ORD) for ten years. With the EPA, I served as Branch Chief of the Chemical Mixtures Assessment Branch and Acting Director of the Environmental Criteria and Assessment Office (ORD).

I have been the recipient of the U.S. EPA Bronze Medal four times and continue to serve on a number of EPA advisory committees. I have also served in a similar capacity for the Departments of Justice, Energy, and Defense and other federal agencies, the World Health Organization (WHO) and a range of foreign countries in Europe, Asia, South America and Africa. I am an author/co-author of over 200 peer-reviewed publications and have served on the editorial/review boards of over ten professional journals.

I have been a charter member of the World Health Organizations' Steering Group for Risk Assessment since 1994, and I am a member of the American College of Toxicology, the American Association for the Advancement of Science, and the Research Society of North America and other professional organizations. I am one of 180 elected fellows of the Collegium Ramazzini in the world, a credentialed member of the Senior Biomedical Research Service (1998-2007) and now am classified as a "Distinguished Consultant". (ATSDR/CDC).

The ATSDR is one of eight operational units within the Department of Health and Human Services, and is co-located with the CDC in Atlanta, Georgia.

The mission of ATSDR is "to serve the public by using the best science, taking responsive public health actions, and providing trusted health information to prevent harmful exposures and disease related to toxic substances." It is the primary Federal agency that addresses the health mandates of the Comprehensive Emergency Response, Compensation and Liability Act (CERCLA) often referred to as Superfund.

ATSDR's mission is remarkably congruent with my own personal mission statement that is "to be an advocate for public health by translating science into public health service and policy". My opinions regarding the range of potential health affects to Formaldehyde exposure are those articulated in ATSDR's Toxicological Profile on this substance. ATSDR's Toxicological Profiles on priority chemicals are peered and publicly reviewed in accordance with the Superfund Authorization Reauthorization and Amendment Act (SARA 1994).

There are a range of activities and programs that have been developed to fulfill CERCLA public health mandates. One of these is a "Health Consultation", developed as a formal response to what may be time sensitive issues as was the case in the aftermath of Hurricane Katrina, which occurred in August 2005. Following the Agency's initial response to this tragic event, ATSDR was also engaged in ongoing verbal and written evaluations and discussions for a wide range of information on behalf of EPA and FEMA.

This included the evaluation of formaldehyde levels in the air of unoccupied FEMA trailers. In contrast to a Health Consultation, such evaluations are more informal, usually verbal,

periodic discussions of available data. Initial discussions regarding sampling protocols and data collection of formaldehyde in trailers used by the EPA began in late June of 2006.

Because of the sensitivity of emergency event, preparedness and coordination activities, I began weekly reports in 1999 for all senior staff including senior Agency leadership. These reports summarized significant events in these often, time sensitive programmatic areas. The details regarding the work we did in support of EPA and FEMA were frequently reported in these reports.

In early December of 2006, Dr. Howard Frumkin stated to me that I had not kept him adequately informed of the fact that we were evaluating air samples from FEMA trailers collected by EPA and in support of EPA's efforts following Hurricane Katrina. I advised Dr. Frumkin that this was the product of a routine collaboration between ATSDR and EPA for approximately 25 years for time sensitive events involving environmental contamination. These efforts had been reported frequently in the weekly reports to senior management. Dr. Frumkin requested that his name be deleted from the mailing list for these weekly reports in September of 2007 since he found them to be unhelpful.

In early December 2006, two members of my division's Emergency Response Team (ERT) were asked to provide an evaluation of EPA's sampling data regarding the levels of formaldehyde in unoccupied trailers. Dr. Frumkin was aware of this evaluation as early as December 4, 2006. At the specific direction of FEMA's attorney, these two members of my division's ERT did not share the evaluation through the usual division review and approval channels. Instead they provided the drafts of the consultation to the Director's Office for Preparedness, Terrorism and Emergency Response (OPTER). However, this was done without my knowledge and I was unaware of the role of Dr. Frumkin's office in the oversight of this effort until summer 2007. It was through this channel that Drs. Frumkin and Sinks provided review and comment on the draft Health Consultation.

During the period intervening between the point at which the sampling data was provided to my division's ERT by FEMA's Office of Legal Council (OLC) on December 4, 2006 and the release of the Health Consultation to FEMA on February 1, 2007, Drs. Sinks and

Frumkin provided review and comment on the draft consultation. During this period, at no time did I have contact with either FEMA or EPA on this issue.

This Health Consultation was forwarded to FEMA on February 1, 2007. I was unaware of this until the receipt of the Health Consultation on February 27, 2007, when a copy of the report appeared on my desk. After an initial review of the Health Consultation, I immediately contacted Dr. Frumkin's office by telephone and email to state my concerns regarding the limitations of the Health Consultation. I stated that the report failed to address longer term health effects especially the issue that formaldehyde is a carcinogen. That same day I sent a second email transmitting a proposed amendment to the consult to address these longer term health concerns.

After repeated requests to issue an amendment to the original consult, I was directed by Dr. Frumkin to forward my proposed response to Dr. Mark Keim, acting Director of the Office of Preparedness, Terrorism and Emergency Response. This letter amending the February 1st consult was subsequently sent to FEMA over the signature of Dr. Mark Keim on March 17, 2007. At this point, I concluded that the lead for this effort resided solely within the Office of the Director.

I had no further formal involvement with the FEMA consultation until late June, 2007, when an impromptu briefing for Congressional Staff occurred, regarding this issue. However, in the interim, I repeatedly cautioned Dr. Frumkin and other senior staff regarding the formaldehyde issue in FEMA trailers. For example, on June 1, 2007, I wrote to Dr. Frumkin outlining my concerns in response to a request from FEMA to identify "safe levels of formaldehyde exposure". I cautioned that since formaldehyde is a carcinogen, it is a matter of U.S. Federal Government science policy, that there is technically no "safe level" of exposure. I wrote that the Department of Health and Human Services had classified formaldehyde as "reasonably anticipated to be a human carcinogen". I also wrote that in 1995, the World Health Organization's (WHO), International Agency for Research on Carcinogens (IARC) had classified formaldehyde as "probably carcinogenic to humans" while EPA had determined that formaldehyde is a "probable human carcinogen".

I further cautioned that:

- formaldehyde may be a reproductive and developmental toxicant;
- it is a irritant as evidenced by the reported symptoms of the children in the trailers in Mississippi; and
- that the overt symptoms would probably trigger sensitization in some proportion of the population, to varying degrees in children and others housed in the FEMA trailers.

I also recommended that ATSDR's Health Guidance Values for short term, intermediate and long term exposures to formaldehyde be used in assessing the hazards posed by formaldehyde in the FEMA trailers. Dr. Frumkin concurred with my concerns with an email response.

Finally, I wrote that to my knowledge this was the third time that we had been approached by FEMA requesting that we provide health guidance on safe levels of exposure to formaldehyde and that we restrict our evaluation to short term exposures.

The first instance occurred in the Spring of 2006 when FEMA requested that I review a draft statement that encompassed only the short term health information that had been abstracted from our Toxicological Profile. I indicated that FEMA had neglected to address longer term exposures and indicated that failure to address longer term health effects could be misleading.

Subsequently, starting in the summer of 2007, particularly after Congressional hearings and reports in the media, I repeatedly requested that we initiate health interventions to interdict these exposures and mitigate health effects. This was based on reports of acute clinical signs consistent with formaldehyde toxicity and presented by residents of FEMA trailers. Most importantly, I pointed to the primal need to alert the trailer residents regarding all health hazards.

In August 2007, ATSDR began to respond to Congressional requests for documents related to the FEMA trailers. It was during this time that I first became aware that the scope and content of the February 1st consult was specifically directed by Dr. Frumkin's office. Drs.

Frumkin and Sinks and senior management of Dr. Frumkin's OPTER, had reviewed and/or had been made aware of the ongoing evaluation of sampling data on behalf of FEMA as early as December 2006. Mr. Don Benkin then Acting Director for OPTER, was involved from the beginning of this activity dating back to June 19, 2006.

In discussing this issue at the weekly Senior Staff meeting on Aug 29, 2007, Dr. Frumkin addressed the need for all staff to grasp the broader public health implications of any request we received from outside agencies. He indicated that it was a failure of my division's ERT to take into account the broader implications of the FEMA request by restricting the review to short term exposures only (as directed by FEMA's Office of Legal Council), even though the ERT believed they were following the instructions issued by Dr. Frumkin's office.

As our efforts in the Gulf Coast Region and elsewhere went forward, I repeatedly requested (albeit without success), that health interventions be pursued to address the clinical manifestations of acute formaldehyde toxicity presented in clinical settings by residents of the FEMA trailers. I stated that such clinical signs were a "harbinger of a pending public health catastrophe" that may be "transgenerational" in its impact. I stressed the importance of alerting the trailer residents to the potential reproductive, developmental and carcinogenic effects of formaldehyde exposure.

The only response I received was that such matters should not be discussed in emails since they might be "misinterpreted." In March of 2007, after I reviewed a draft of CDC Director, Dr. Julie Gerberding's proposed response to Congressman Taylor's letter, I responded that there was still no mention of carcinogenicity and that it was not appropriate to compare formaldehyde exposures in trailers to that of conventional housing.

Based upon follow up discussions with my ERT staff regarding the February Health Consultation it was clear to me, Drs. Frumkin and Sinks provided review and comment on multiple occasions prior to the development of the Health Consultation and that they must have been aware of the content and scope of the February 1st consult. I found this to be deeply troubling since the Emergency Response Team's efforts were now being identified as the primary basis for Congressional concerns about the scope and nature of the Agency's conclusions as stated in the first Health Consultation. Internally, Dr. Frumkin stated that the

ERT should have been aware of the broader implications of the FEMA request particularly since it involved FEMA's Office of Legal Council.

On August 10, 2007 Dr. Frumkin assigned to my division the lead to develop a revised Health Consultation based upon the sampling data provided by FEMA. On September 19, 2007, I forwarded a draft, but unedited, revised consultation, to Dr. Frumkin in response to his comments received the previous day.

At that point the document had been completed to the satisfaction of three other divisions within ATSDR who had been involved in the review, data analysis and authorship of the revised consultation. The following day Dr. Frumkin reassigned the lead to his Office of Science. The resulting consultation that appeared in October was notable in that the executive summary was changed to read that health interventions to interdict exposures and or mitigate health effects should be "identified" as opposed to "identified" and "implemented". Further, some of the references addressing reproductive and developmental effects were deleted.

Based upon my concerns, as previously outlined, I wrote a letter on September 21st addressing these and other issues were based on important health findings were not being shared with the public. In this letter I requested a meeting with senior management to identify "a constructive path forward". Drs. Falk, Frumkin, Sinks, and Louise Galaska met with me on October 5, 2007.

At that meeting, I was asked what I proposed as a constructive path forward. In response to that question, I stated that it was my hope that they would provide such guidance, since I had already stated my concerns in my letter of September 21, 2007. In response, they stated that they had no guidance to provide. As a result, the meeting was adjourned within 15 minutes and I was told by Dr. Frumkin that he would provide a written response to my letter.

After my September 21st letter to Dr. Frumkin, my evaluation, which was scheduled for October 4, 2007, was then deferred until October 22, 2007. The meeting was then rescheduled three different times. Originally it was scheduled to be at 7:30 AM, then at 4:00PM and then finally at 3:00PM. Drs. Frumkin and Sinks knew that I was preparing to leave on international travel within the next hour of the appointment scheduled 3:00 pm. The proposed evaluation of

my performance was not presented to me for review five days in advance in accordance with Agency guidelines and policy. Due to complications in preparing for my travel, the evaluation was done telephonically, as it was done in the previous evaluation cycle. I was told that my evaluation was "unsatisfactory". When I asked why, I was told that I was not a "team player".

Subsequently my written evaluation was presented to me by Dr. Frumkin three minutes before the beginning of the Ramazzini Award Ceremony and Presentation in Carpi, Italy. This was done in a public forum, in the presence of my father, who attended the meeting as my guest, as well as colleagues with whom I was seated near the front of the auditorium. At that same time, Dr. Frumkin also presented me with a memorandum stating that I was being removed from my position as Division Director. This memorandum stated that I was being reassigned to a position that had no job description until December 20, 2007. Since this was the first day of my annual holiday leave, I did not receive the written job description until January 7, 2008 when I returned to work. My office was moved in November 2007; in December 2007 and again in February 2008 involving three offices and two geographic locations.

In summary, I was removed from my position after 16 years of superior performance and having met or exceeded 95% of all of my division's performance objectives in the past three years. In 2006, an independent year long external peer review of all division activities concluded that my former division was "meeting an important national need", that our Division's consensus based "goals and objectives" were consistent with this "national need and the mission of the Agency" and was "performing at a high level".

As a voting member of the credentialing committee for the Senior Biomedical Research Service since 1998, one of 180 elected Fellows of the Collegium Ramazzini, and having served on the editorial boards for over 10 professional journals, I know that scientists can make mistakes. However, the only rationale provided to me at the time of my evaluation was that I was not a "team player". There were no written narratives associated with the evaluation presented to me in Italy, addressing the rationale for the elements in my performance plan that were rated as unsatisfactory.

As documented in my curriculum vitae, I have served as an expert witness on behalf of the U.S. Government on multiple occasions (in which the government prevailed). I currently

serve on approximately 25 committees of national and international significance and have served as author or co-author on approximately 200 publications. I have made numerous invited and plenary presentations on behalf of multiple organizations, including: the National Academy of Sciences, the Institute of Medicine and the National Institutes of Health, The EPA, and the WHO. Nevertheless, in Dr. Frumkin's response to my September 21st letter, he maligned my technical ability, communication skills, managerial competence and my professional reputation.

The issues addressed in my testimony today, as well as others conveyed in my September 21, 2007 memo to Dr. Frumkin presented me with a profound professional dilemma. In addressing this dilemma, I recalled a framed document entitled The Centers for Disease Control and Prevention's "Pledges to the Citizens of the United States" which was displayed in my former office. One of the five points in this pledge, that served as a key point in my own deliberative process was that "We will place the benefit to society above the benefits to the institution". I also recalled the first time when I was undergoing the background investigation for top secret security clearance several years ago. The best advice I was given was to "speak the truth even when it hurts". Finally, I recalled the central core of public health practice and environmental medicine first articulated by Bernardino Ramazzini four centuries ago. "That it is better to prevent than cure". This is what I have attempted to do addressing the FEMA trailers issue. This is what I am continuing to pursue in this and other matters.

In addition to the FEMA consultation, my letter of September 21, 2007 also addressed the Great Lakes Report and the presence of the carcinogen 1,4-Dioxane in baby shampoos, bubble bath and approximately 30% of cosmetic products. These were the three issues that were addressed in Dr. Frumkin's response to my letter, and that were used to justify my unsatisfactory rating. I pursued these issues because I believe important public health information, that had been vetted in accordance with all Agency review and clearance procedures, was being withheld from the public. Accordingly, it was not available to promote the best informed public health decisions by citizens, community leaders, health care professionals and those responsible for the oversight of public health more generally.

Given the visibility of my former position within the Agency, and what had been viewed as a respected contribution to the Agency's goals and mission, my removal, which closely

followed my attempt to speak the truth to authorities, sends a chilling message, not only to other Agency employees, but to all federal employees and more importantly those dependent upon support from our nation's federal agencies. Citizens of the United States who pay for the services provided by these agencies should benefit from the best possible scientific information in a timely, responsive, and responsible fashion. Because of my commitment to this concept, it is my ardent desire to be reinstated to my former position as Director of the Division of Toxicology and Environmental Medicine which has been the very heart of my professional career.

I would like to express my sincere thanks to the Members and staff of this Subcommittee for their time and attention concerning these matters.